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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/960,244	09/21/2001	Tony W. Ho	2831.2003-000	4326

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EXAMINER

SAUCIER, SANDRA E

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 01/08/2003

11

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/960,244

Applicant(s)

Ho et al.

Examiner

Sandra Saucier

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-- Th MAILING DATE of this communication appears on th cover sh et with the correspond nce address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1035 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-96 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 1-96 are subject to restriction and/or election requirements.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other: _____

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DETAILED ACTION

Claims 1-96 are pending and subject to restriction.

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claim 1-13, drawn to a cell population which expresses CD49c, CD90 and telomerase, classified in class 435, subclass 372.
- II. Claims 14-26, drawn to cell population which expresses CD49c and CD90, but not sialoprotein, classified in class 435, subclass 372.
- III. Claims 27-45, 47, 48 drawn to a first method of making a population which expresses CD49c and CD90 comprising a one step culturing process of seeding a source at less than about 100 cells/cm², classified in class 435, subclass 377 and others.
- IV. Claims 46, 49-60 drawn to a second method of making a population which expresses CD49c and CD90 comprising a two step culturing process of seeding a source and a subsequent subculturing of the adherent cells, classified in class 435, subclass 377 and others.
- V. Claim 61, drawn to a method of treating a human suffering from a degenerative or acute injury comprising administering cell population which expresses CD49c and CD90, classified in class 424, subclass 93.7.
- VI. Claim 62, 63, 65-72 drawn to a method of treating a human suffering from a neurological condition comprising administering cell population which expresses CD49c and CD90, classified in class 424, subclass 93.7.
- VII. Claim 64, drawn to a method of treating a human suffering from a cardiac condition comprising administering cell population which expresses CD49c and CD90, classified in class 424, subclass 93.7.

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- VIII. Claims 73–77, drawn to a method of making a committed progenitor cell comprising modifying cells which express CD49c and CD90 classified in class 435, subclass 377.
- IX. Claim 78, drawn to a method of treating a human suffering from a degenerative or acute injury comprising administering cell population which expresses CD49c and CD90 and telomerase classified in class 424, subclass 93.7.
- X. Claims 79–87, drawn to a method of treating a human suffering from a neurological condition comprising administering cell population which expresses CD49c and CD90 and has been modified to become a committed progenitor cell classified in class 424, subclass 93.7.
- XI. Claims 88–92, a pharmaceutical composition comprising a cell population which expresses CD49c and CD90 classified in class 424, subclass 93.7.
- XII. Claim 93, a pharmaceutical composition comprising a cell population which expresses CD49c and CD90 and telomerase classified in class 424, subclass 93.7.
- XIII. Claim 94, drawn to a method of treating a human suffering from a neurological condition comprising administering cell population which expresses CD49c and CD90 and telomerase classified in class 424, subclass 93.7.
- XIV. Claim 95, drawn to a method of treating a human suffering from a degenerative or acute injury comprising administering cell population which expresses CD49c and CD90 and bone lineage marker classified in class 424, subclass 93.7.
- XV. Claim 96, drawn to a method of treating a human suffering from a neurological condition comprising administering cell population which expresses CD49c and CD90 and bone lineage marker classified in class 424, subclass 93.7.

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The inventions are distinct, each from the other because of the following reasons:

Groups I and II are distinct cells with distinct characteristics.

Groups III, IV and VIII are distinct methods of producing cells with distinct steps and end products.

Groups V-VII, IX, X, XIII-XV are distinct methods of treating distinct patients with distinct compositions.

Groups XI and XII are distinct composition comprising cells with distinct characteristics in a pharmaceutical form.

Groups III, IV or VIII are not method of making the composition of Group I or II because, for example, the cells of Group I express telomerase, while the cells made by the processes of III, IV or VIII are not required to express telomerase and the cells made by the processes of III, IV or VIII are not required to be negative for the expression of sialoprotein.

Groups XI and XII are not made by the processes of Groups III, IV or VIII because the products of the process are not required to be in pharmaceutical form.

The process of treating humans of Groups V, VI, VII, X, XIV, XV do not require the composition of Groups I or II because the compositions used in Groups V and VI do not require expression of telomerase or non-expression of sialoprotein.

Inventions I and IX, XIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the cells of Group I can be used to raise antibodies or to treat distinct conditions as claimed in claims 78, 94.

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The several inventions listed above are independent and distinct from one another as they have acquired a separate status in the art and require independent searches, particularly with regard to the literature searches. Clearly, a reference which would anticipate one of the above groups would not necessarily anticipate or even make obvious any of the others.

An undue burden would ensue from the examination of multiple methods which have distinct steps and end points. Burden lies not only in the search of US Patents, but in the search for literature and foreign patents and examination of the claim language and specification for compliance with the statutes concerning new matter, distinctness and scope of enablement.

Because these inventions are distinct for the reasons given above restriction for examination purposes as indicated is proper.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1651. The supervisor for 1651 is M. Wityshyn, (703) 308-4743. The normal work schedule for Examiner Saucier is 8:30AM to 5:00PM Monday and Tuesday and 8:30 to noon on Wednesday.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Saucier whose telephone number is (703) 308-1084. Status inquiries must be directed to the Customer Service Desk at (703) 308-0197 or (703)-308-0198. The number of the Fax Center for the faxing of papers is (703) 308-2742 or (703) 305-3592.

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A handwritten signature in black ink, appearing to read 'S. Saucier', with a stylized flourish extending to the right.

Sandra Saucier
Primary Examiner
Art Unit 1651
January 7, 2003